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JUN 25 2001		TRANSMITTAL LETTER		Petitioner's Case No. 5050/296
Serial No. 08746360	Filing Date November 8, 1996	Examiner F. Jaworski	Group Art Unit 3305	
Inventor(s) Ted Christopher				
Title of Invention Finite Amplitude Distortion-Based Inhomogeneous Pulse Echo Ultrasonic Imaging				

To the Commissioner for Patents:

- ☒ Transmitted herewith is a "Reply in Support of Petitioner's Motion to Suppress the Declarations of Applicant's Rebuttal Witnesses," "Petitioner's Opposition to Applicant's Motion to Suppress Evidence (Petitioner Exhibit Nos. 5-9 and 13-20)," "Petitioner's Opposition to Applicant's Motion to Suppress Evidence (Petitioner Exhibit No. 23)," and a Postcard Receipt.
- ☐ Small entity status of this application under 37 CFR § 1.27 has been established by verified statement previously submitted.
- ☐ A verified statement to establish small entity status under 37 CFR §§ 1.9 and 1.27 is enclosed.
- ☐ Petition for a \_\_\_\_\_ month extension of time.
- ☒ No additional fee is required.
- ☐ Please charge my Deposit Account No. 23-1925 in the amount of \$: \_\_\_\_\_. A duplicate copy of this sheet is enclosed.
- ☒ The Commissioner is hereby authorized to charge payment of any additional fees associated with this communication or credit any overpayment to Deposit Account No. 23-1925. Further, I hereby petition under 37 CFR § 1.136 for any extension of time required to ensure that this paper is timely filed. A duplicate copy of this sheet is enclosed.

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Respectfully submitted,

June 25, 2001  
Date

Joseph F. Hetz  
Registration No. 41,070  
Attorney for Petitioner

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Express Mail Number: EL573464445US  
Date of Mailing: June 25, 2001

Petitioner's Case No. 5050/296

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Public Use Proceeding	)	
For the Application of:	)	
Ted Christopher	)	
Serial No.:	)	Examiner: F. Jaworski
08/746,360	)	
Filed:	)	Group Art Unit: 3305
November 8, 1996	)	
For:	)	
Finite Amplitude Distortion-	)	
Based Inhomogeneous	)	
Pulse Echo Ultrasonic	)	
Imaging	)	

**REPLY IN SUPPORT OF**  
**PETITIONER'S MOTION TO SUPPRESS THE DECLARATIONS OF**  
**APPLICANT'S REBUTTAL WITNESSES**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

In accordance with 37 C.F.R. § 1.638(b), Petitioner submits this Reply in Support of Petitioner's Motion to Suppress the Declarations of Applicant's Rebuttal Witnesses.

In its opposition, Applicant argues that Petitioner does not have the right to cross-examine the rebuttal declarants because this public use proceeding is an *ex parte* proceeding. However, the *ex parte* nature of this proceeding does not prohibit cross-examination of the rebuttal declarants. The MPEP and the public use proceeding schedule and rules make clear that there should be only four differences between *ex parte* and *inter partes* public use proceedings. In an *ex parte* public use proceeding, (1) the

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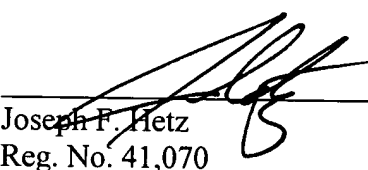
petitioner cannot inspect the contents of the application,<sup>1</sup> (2) the petitioner cannot receive a copy of the Examiner's memorandum setting forth the *prima facie* case of public use,<sup>2</sup> (3) an oral hearing is not held,<sup>3</sup> and (4) the petitioner's participation in the prosecution of the application ends after the Examiner makes his final decision.<sup>4</sup> There is absolutely no prohibition against Petitioner cross-examining Applicant's rebuttal declarants.

Because it would be manifestly unfair for the Examiner to rely upon any declarations of Applicant's witnesses that have not been provided "in accordance with normal rules of evidence, including the right of cross-examination,"<sup>5</sup> Petitioner respectfully requests that the Evidentiary Declarations of Kim A. Baker, Kevin J. Parker, and Evan C. Unger, MD be suppressed.

Dated: June 25, 2001

Respectfully submitted,

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Attorney for Petitioner

<sup>1</sup> MPEP 720: "In the *ex parte* situation, the petitioner is not entitled, as a matter of right, to inspect the pending application. . . . In the *inter partes* situation, the petitioner is privy to the contents of the pending application."

<sup>2</sup> MPEP 720.03: "In *ex parte* cases, whether or not the examiner has concluded that a *prima facie* showing has been established, no copy of the examiner's memorandum to the Patent Legal Administrator will be forwarded to petitioner."

<sup>3</sup> Public Use Proceeding Schedule, page 2: "Since this is an *ex parte* case, no oral hearing will be held."

<sup>4</sup> 37 C.F.R. § 1.292(a): "The petitioner will be heard in the proceeding but after decision therein will not be heard further in the prosecution of the application for patent."

<sup>5</sup> MPEP 720.04: "The statutory bar can only be established by testimony taken in accordance with normal rules of evidence, including the right of cross-examination."

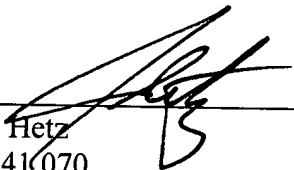
**PROOF OF SERVICE**

In accordance with 37 C.F.R. § 1.248, Petitioner hereby certifies that a duplicate copy of this paper has been served on Applicant's attorney on June 25, 2001 via first class mail at the following address:

John S. Sensny, Esq.  
Scully, Scott, Murphy & Presser  
400 Garden City Plaza  
Garden City, New York 11530-0299

Dated: June 25, 2001

Respectfully submitted,

  
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Express Mail Number: EL573464445US

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Petitioner's Case No. 5050/296

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Public Use Proceeding )  
For the Application of: )  
Ted Christopher )  
Serial No.: 08/746,360 )  
Filed: November 8, 1996 )  
For: Finite Amplitude Distortion- )  
Based Inhomogeneous )  
Pulse Echo Ultrasonic )  
Imaging )

Examiner: F. Jaworski

Group Art Unit: 3305

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**PETITIONER'S OPPOSITION TO**  
**APPLICANT'S MOTION TO SUPPRESS EVIDENCE**  
**(PETITIONER EXHIBIT NOS. 5-9 AND 13-20)**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

In accordance with 37 C.F.R. § 1.638(a), Petitioner submits this Opposition to Applicant's Motion to Suppress Evidence (Petitioner Exhibit Nos. 5-9 and 13-20).

Petitioner Exhibit Nos. 5-9 and 13-20 are still frames taken from the moving images recorded on the videotapes marked Petitioner Exhibit Nos. 1 and 11, respectively. On page two of its motion, Applicant asserted that Petitioner Exhibit Nos. 5-9 and 13-20 are not evidentiary and should be suppressed because the still frames "do not form part of anything that the public witnesses [sic] or could have witnessed at the relevant time - or ever." This simply is not true. The images shown in Petitioner Exhibit Nos. 5-9 and 13-20 form part of the moving images that *were shown to the public* (the Acuson Images). When the public saw the Acuson Images, they necessarily saw the images shown in

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Petitioner Exhibit Nos. 5-9 and 13-20. Accordingly, there is nothing unfair or prejudicial about the use of these exhibits.

The videotapes are the primary evidence in this proceeding. Petitioner has asserted that the moving right-hand-side images shown from 5:36:05 to 5:39:03 in the Betacam videotape marked Petitioner Exhibit No. 11 (the Acuson Images) and the moving images shown from 8 minutes to about 8 minutes, 8 seconds in the VHS videotape marked Petitioner Exhibit No. 3 (the Mayo Clinic Images) were in public use.<sup>1</sup> Petitioner's witnesses have clearly stated that their analysis was based on the moving images shown in the videotapes — not based on the still frames alone.<sup>2</sup>

However, Petitioner provided the still frames as additional evidence to aid the Examiner—in effect, a summary of the videotaped evidence pursuant to Federal Rule of Evidence 1006. Although Petitioner encourages the Examiner to view the videotape evidence, Petitioner Exhibits Nos. 5-9 and 13-20 provide the Examiner with the convenience of reading the briefs in this proceeding without reference to the videotapes. Also, Petitioner Exhibit Nos. 13-20 may be the only practicable way of making the contents of Petitioner Exhibit No. 11 available to the Examiner. Petitioner Exhibit No.

---

<sup>1</sup> Petitioner's Brief, page 2.

<sup>2</sup> "I compared the left-hand-side images, which -- which are standard -- *I'm speaking now about the videotape, not the -- not the exhibits which represent stills from that videotape.*" Dep. of Gregory L. Holley, Petitioner Page 82, lines 19-22.

"The right-hand image shown *in the portions of the Acuson Tape around Frame D* . . . show[s] Tissue Harmonic Images of animal tissue . . . ." Sec. Evid. Dec. of Gregory L. Holley ¶15, Petitioner Page 11 (emphasis added).

"This observation corroborates my opinion that *the image shown in the right-hand side image* before the arrival of contrast agent in the left ventricle (*from time code 5:36:05 to time code 5:39:03*) is a Tissue Harmonic Image." Third Evid. Dec. of Gregory L. Holley ¶15, Petitioner Page 30 (emphasis added); Sec. Evid. Dec. of Joan C. Main ¶27, Petitioner Pages 22-23 (emphasis added).

11 is a Betacam videotape that cannot be played on a conventional VCR or Betamax player (Betacam and Betamax are different formats). Petitioner recognizes that the Examiner may not have access to a Betacam player, which can cost over \$10,000, and Petitioner Exhibit Nos. 13-20 may be the only way for the Examiner to analyze the Tissue Harmonic Images referenced by the time codes unique to Petitioner Exhibit No. 11.


The use of such summary exhibits as Petitioner Exhibit Nos. 13-20 is authorized by Rule 1006 of the Federal Rules of Evidence: "The contents of voluminous writings, recordings, or photographs *which cannot conveniently be examined in court* may be presented in the form of a chart, summary, or calculation" (emphasis added). Like voluminous writings, recordings, or photographs, a videotape that can be viewed only with expensive, professional video equipment may not be conveniently examined in the Patent and Trademark Office. The same is true, although to a lesser extent, for the VHS videotapes of Petitioner Exhibit Nos. 5-9. Accordingly, still frames are appropriate evidence in this proceeding.

For the reasons set forth above, Petitioner respectfully requests that the Examiner deny Applicant's Motion to Suppress Petitioner Exhibits Nos. 5-9 and 13-20.

Dated: June 25, 2001

Respectfully submitted,

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\_\_\_\_\_  
Joseph P. Hetz  
Reg. No. 41,070  
Attorney for Petitioner


**PROOF OF SERVICE**

In accordance with 37 C.F.R. § 1.248, Petitioner hereby certifies that a duplicate copy of this paper has been served on Applicant's attorney on June 25, 2001 via first class mail at the following address:

John S. Sensny, Esq.  
Scully, Scott, Murphy & Presser  
400 Garden City Plaza  
Garden City, New York 11530-0299

Dated: June 25, 2001

Respectfully submitted,

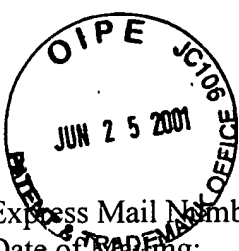


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Pulse Echo Ultrasonic )  
Imaging )

Examiner: F. Jaworski  
Group Art Unit: 3305

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**PETITIONER'S OPPOSITION TO**  
**APPLICANT'S MOTION TO SUPPRESS EVIDENCE**  
**(PETITIONER EXHIBIT NO. 23)**

Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

In accordance with 37 C.F.R. § 1.638(a), Petitioner submits this Opposition to  
Applicant's Motion to Suppress Evidence (Petitioner Exhibit No. 23).

**FACTS**

1. On February 6, 2001, Petitioner submitted a 37 C.F.R. § 1.673(b) List of Documents and Things. At the time the 37 C.F.R. § 1.673(b) List was filed, Petitioner's attorneys were not aware of Petitioner Exhibit No. 23. Accordingly, Petitioner Exhibit No. 23 was not identified on the 37 C.F.R. § 1.673(b) List.

2. On March 13, 2001, Applicant took the deposition of Janna G. Clark. A secretary for Petitioner's attorneys interrupted the deposition of Ms. Clark and

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announced: "Joan Main called and said she found the tape." Applicant's attorneys were present when the secretary made this announcement.

3. In the evening of March 13, 2001, Ms. Main provided Petitioner's attorneys with a Betacam tape labeled "ACUSON COMPUTED SONOGRAPHY 1994 Contrast Investigation And 3D/4D Imaging LOOPED BETACAM SP DUB SUB TRT: 30:00" (the "1994 Betacam tape"). Petitioner's attorneys were not aware of the 1994 Betacam tape before March 13, 2001. Ms. Main had not located it until that date either, as she testified at her deposition the next day.

4. Ms. Main's deposition took place on March 14, 2001. Before the deposition began, Petitioner's attorney notified Applicant's attorneys of the 1994 Betacam tape. Petitioner's attorney invited Applicant's attorneys to view the 1994 Betacam tape and use it during the cross-examination of Ms. Main, if they desired.

5. Before Applicant's attorney began his cross-examination of Ms. Main, Petitioner's attorney described, for the record, the conversation that took place with Applicant's attorneys and the physical features of the 1994 Betacam tape. Petitioner's attorney did not offer the 1994 Betacam tape into evidence or ask Ms. Main any questions about the tape.

6. During cross-examination, Applicant's attorney "opened the door" by asking Ms. Main several questions about the 1994 Betacam tape:

Q. Did you continue to show this tape after you added more things to the presentation?

A. Oh, yes.

Q. Was the tape the same tape?

A. It was an expanded version of the same data, yes.

Q. *Do you know how that expanded version [the 1994 Betacam tape] was made?*

A. Yes.

Q. *How was it made?*

...

Q. In your previous answer, you indicated that you had given the studio more raw data, and it was added on to this portion of the tape. Do you recall that?

A. I recall that.

Q. Okay. Now, in that answer, when you said "the tape," *what tape are you referring to?*

...

A. I'm sorry. In a new tape [the 1994 Betacam tape].<sup>1</sup>

7. To conduct a proper re-direct examination of Ms. Main on this matter, Petitioner's attorney marked the 1994 Betacam tape as Petitioner Exhibit No. 23 and offered it into evidence.

8. At 11:30 a.m., Petitioner's attorney played Petitioner Exhibit No. 23 and offered "to stay here as long as it takes to get questions asked and answered of Ms. Main regarding this tape."<sup>2</sup> The parties had planned the deposition of Ms. Main to proceed for the entire day. At 11:35 a.m. with Petitioner Exhibit No. 23 still playing on a video monitor, Applicant's attorneys ended the deposition of Ms. Main without asking Ms. Main any additional questions about Petitioner Exhibit No. 23. Applicant's attorneys provided no good reason why they could not continue to ask questions about Petitioner Exhibit No. 23.

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<sup>1</sup> Dep. of Joan C. Main, Petitioner Page 458, line 13 - Petitioner Page 460, line 14 (emphasis added).

<sup>2</sup> Dep. of Joan C. Main, Petitioner Page 492, lines 11-13.

9. Petitioner's attorney offered to provide Petitioner's witnesses for further cross-examination on Petitioner Exhibit No. 23.<sup>3</sup> Applicant's attorneys did not request further cross-examination of Petitioner's witnesses.

### ARGUMENT

Applicant argues that Petitioner Exhibit No. 23 should be suppressed because it was not listed on Petitioner's 37 C.F.R. § 1.673(b) List of Documents and Things. However, this argument rests on a rule that is not at issue here — 37 C.F.R. § 1.673(c). 37 C.F.R. § 1.673(c) states that a party is not permitted to rely on any thing not listed in its 37 C.F.R. § 1.673(b) List of Documents and Things. However, 37 C.F.R. § 1.673(c) does not apply to depositions for the purpose of cross-examination, as is the situation here. The applicable rule is 37 C.F.R. § 1.672(d).<sup>4</sup>

37 C.F.R. § 1.672(d) states that a party is not entitled to rely on any document or thing at cross-examination if that document or thing was not mentioned in its original or supplemental declarations.<sup>5</sup> This rule contains one important exception: a party is permitted to rely on a document or thing at cross-examination even if that document or thing was not mentioned in the party's original or supplemental declarations "*to the extent necessary to conduct proper redirect.*"

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<sup>3</sup> Dep. of Joan C. Main, Petitioner Page 493, line 20 - Petitioner Page 494, line 1.

<sup>4</sup> 37 C.F.R. § 1.672(d): "At any deposition for the purpose of cross-examination of a witness, the party shall not be entitled to rely on any document or thing not mentioned in one or more of the affidavits filed under paragraphs (b) and (c) of this section, except to the extent necessary to conduct proper redirect."

<sup>5</sup> Petitioner Exhibit No. 23 was not mentioned in the original or supplemental declarations because Petitioner's attorneys were not aware of the exhibit at the time those declarations were filed.

The exception specified in 37 C.F.R. § 1.672(d) addresses the exact situation Petitioner faced when Applicant's attorney questioned Ms. Main about the 1994 Betacam tape. During cross-examination of Ms. Main, Applicant's attorney asked Ms. Main to identify the 1994 Betacam tape<sup>6</sup> and to describe how that tape was made.<sup>7</sup> To conduct a proper re-direct examination on this matter, Petitioner's attorney marked the 1994 Betacam tape as Petitioner Exhibit No. 23 and offered it into evidence, pursuant to § 1.672(d).

Applicant's arguments on this issue are unpersuasive. In its motion, Applicant asserts that it did not solicit any testimony from Ms. Main regarding Petitioner Exhibit No. 23. As shown by the passages quoted above, this assertion is just plain wrong. Applicant also asserts that § 1.672(d) does not apply because Petitioner's attorney identified the 1994 Betacam tape on the record before the cross-examination began. However, Petitioner's attorney merely made a record of the conversation that took place with Applicant's attorneys. It was Applicant's attorney — not Petitioner's attorney — who questioned Ms. Main about the tape. If Applicant's attorney did not want Petitioner Exhibit No. 23 to be introduced into evidence, he should not have asked Ms. Main about the tape.

Applicant's arguments about how unfair it would be to allow Petitioner Exhibit No. 23 into evidence are equally unpersuasive. Applicant and his attorneys simply did not want to deal with the additional evidence of public use and chose to bury their heads

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<sup>6</sup> "Q. Okay. Now, in that answer, when you said 'the tape,' *what tape are you referring to?*" Dep. of Joan C. Main, Petitioner Page 459, lines 22-23 (emphasis added).

<sup>7</sup> "Q. *Do you know how that expanded version [the 1994 Betacam tape] was made?* . . . Q. *How was it made?*" Dep. of Joan C. Main, Petitioner Page 458, lines 19-21 (emphasis added).

in the sand by not taking advantage of the time and opportunities they had to review and question Petitioner's witnesses about the exhibit. Applicant complains that it did not have time to review the 36 minute videotape (consisting of approximately six looped or repeated sections each six minutes long) yet ended Ms. Main's deposition at 11:35 a.m. instead of spending the rest of the morning and the afternoon reviewing the tape. Applicant also complains that it will need to re-assemble its witnesses and re-open testimony to address Petitioner Exhibit No. 23. However, if Applicant's witnesses needed to review and provide testimony on Petitioner Exhibit No. 23, why didn't they do so during the three-and-a-half weeks after Ms. Main's deposition and before Applicant submitted its rebuttal testimony? Further, if Applicant needed to question Petitioner's witnesses regarding the tape, why didn't Applicant ask Petitioner to provide its witnesses for further cross-examination, as Petitioner's attorney offered? Applicant should not be allowed to argue the fairness of including Petitioner Exhibit No. 23 into evidence when it squandered its opportunities to review and question witnesses about this exhibit.

For the reasons set forth above, Petitioner respectfully requests that the Examiner deny Applicant's Motion to Suppress Petitioner Exhibit No. 23.

Dated: June 25, 2001

Respectfully submitted,



---

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Reg. No. 41,070  
Attorney for Petitioner

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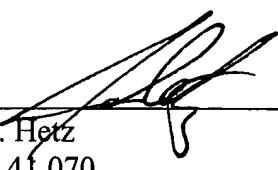
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John S. Sensny, Esq.  
Scully, Scott, Murphy & Presser  
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Garden City, New York 11530-0299

Dated: June 25, 2001

Respectfully submitted,



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Express Mail Number: EL573464079US  
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Petitioner's Case No. 5050/296

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Finite Amplitude Distortion-	)	
Based Inhomogeneous	)	
Pulse Echo Ultrasonic	)	
Imaging	)	

**PETITIONER'S REPLY BRIEF**





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## **I. INTRODUCTION**

The only question before the Examiner is whether the publicly used Acuson Images or Mayo Clinic Images are Tissue Harmonic Images. The evidence has conclusively established that they are, and Applicant has not rebutted this evidence. The pending method and system claims should now be rejected under 35 U.S.C. § 102(b) alone or in combination with 35 U.S.C. § 103.

## **II. APPLICANT'S CONTRIVED DISTINCTIONS DO NOT DIMINISH THE SUBSTANTIAL WEIGHT OF PETITIONER'S EVIDENCE**

### **A. Applicant's Arguments Regarding Videotapes That Were Not Publicly Used Are Completely Irrelevant**

In its brief, Applicant attempts to diminish the importance of the publicly used Acuson and Mayo Clinic Images<sup>1</sup> by complaining that Petitioner has not provided the videotapes containing the ultrasound images originally recorded at the Acuson and Mayo Clinic studies. *These videotapes are completely irrelevant because they were not publicly used.* Contrary to Applicant's assertion, Petitioner is not required to establish a chain-of-custody of the Acuson and Mayo Clinic Images from their genesis to their public use.

The relevant question is whether the publicly used Acuson and Mayo Clinic Images are Tissue Harmonic Images. Petitioner's witnesses analyzed the images that were *actually in public use* and concluded that they are Tissue Harmonic Images. An analysis of the "first-generation" videotapes is neither required nor necessary because

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<sup>1</sup> The "Acuson Images" refer to the right-hand-side images shown from 5:36:05 to 5:39:03 in Petitioner Exhibit No. 11, which are also shown at corresponding portions in Petitioner Exhibit Nos. 1, 10, 12, and 23. The "Mayo Clinic Images" refer to the images shown from 8 minutes to about 8 minutes, 8 seconds in Petitioner Exhibit No. 3, which are also shown at corresponding portions in Petitioner Exhibit No. 2.

those videotapes were not in public use and Petitioner is not relying upon them to establish public use. Applicant's arguments in this regard should be ignored.

**B. The Quality of the Publicly Used Images Was Not "Bumped Up"**

Contrary to Applicant's desperate assertion of some kind of improper conduct by Petitioner, the quality of the Acuson and Mayo Clinic Images was not enhanced or "bumped up." Rather, some of the second generation tapes were videotapes of better initial quality than the earlier tapes. The format of such tapes permitted better time code usage and were used by Petitioner just like a home videotaper uses better quality videotapes for movies or other videos that he wants to save for a library.

Although the publicly used Acuson and Mayo Clinic Images are edited versions of images originally recorded at the Acuson and Mayo Clinic studies, the editing did not modify the quality of the images. During the editing process, a background and some legends were added around the images, but no edits were made to the images.<sup>2</sup> In short, while the editing changed *how* the images were presented, it did not change the *quality* of the images.

Applicant's argument is based on a misrepresentation of the testimony. First, Applicant asserts that the quality of the Acuson Images was "bumped up." However, Mr. Sheldon testified that it was the Mayo Clinic tape — not the Acuson tape — that was "bumped up."<sup>3</sup> Second, Mr. Sheldon testified that "bumping up" merely refers to the process of copying images from a VHS tape (a lower grade tape) to a Betacam tape (a

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<sup>2</sup> Dep. of Janna G. Clark, Petitioner Page 373, lines 12-19; Dep. of John M. Sheldon, Petitioner Page 210, lines 16-23 and Petitioner Page 213, lines 8-11.

<sup>3</sup> Dep. of John M. Sheldon, Petitioner Page 187, lines 6-15; Evid. Dec. of John M. Sheldon ¶ 2, Petitioner Page 13. The Acuson Images were not "bumped up" to Betacam because they were originally recorded on Betacam. Dep. of Janna G. Clark, Petitioner Page 371, lines 6-18.

higher grade tape) so that the time code numbers on the Betacam tape can be used to edit and reference recorded material precisely.<sup>4</sup> Mr. Sheldon made clear that “bumping up” does not affect the *quality* of the image:

Q. Is it fair to say that the Betacam tape would be a more accurate reproduction than VHS?

A. It depends at the time that the recording is made. If your master or original tape is a Betacam tape, it is going to be better than a second-generation VHS tape made from that tape. *The image, regardless to -- regardless to the format, is only going to be as good as the source.*<sup>5</sup>

...  
If we wanted to pull VHS, we would put that up on Beta. Doesn't give us any benefits, it being on Beta, but it does allow us to use the time code.<sup>6</sup>

The quality of the Acuson and Mayo Clinic Images was not enhanced in any way, and the Examiner should accord full weight to those images.

**C. Applicant Has Not Rebutted Petitioner's Substantial Evidence that the Acuson Images Show the Benefits of Tissue Harmonic Imaging**

**1. The Acuson Images Exhibit Characteristic Features of a Tissue Harmonic Image**

Petitioner has conclusively shown that the Acuson Images are Tissue Harmonic Images because they exhibit two characteristic features of a Tissue Harmonic Image: improved contrast resolution<sup>7</sup> and improved detail resolution over a fundamental image.<sup>8</sup>

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<sup>4</sup> Dep. of John M. Sheldon, Petitioner Page 187, lines 6-15 (“we took a *tape* of a lower quality and bumped it up to a higher quality”) (emphasis added).

<sup>5</sup> Dep. of John M. Sheldon, Petitioner Page 181, line 23 - Petitioner Page 182, line 5 (emphasis added).

<sup>6</sup> Dep. of John M. Sheldon, Petitioner Page 199, lines 5-8.

<sup>7</sup> The inventor, Ted Christopher, admitted that improved contrast resolution is a characteristic feature of tissue harmonic imaging. Petitioner Exhibit No. 4, Page 139 (“The results of this study suggest that the finite amplitude distortion of biomedical ultrasonic imaging pulses could be utilized to enhance the contrast resolution of images”).

<sup>8</sup> Applicant argues that knowledge of the operating parameters of the ultrasound system is needed to prove that the Acuson Images are Tissue Harmonic Images. However, because characteristic features of a Tissue Harmonic Image are shown in the Acuson Images, such knowledge is not required.

When exhibited together in combination, they unmistakably identify tissue harmonic imaging. In its brief, Applicant argues that these features are not unique to a Tissue Harmonic Image because they can be obtained by changing various system and video monitor settings. However, if this were true, clinicians would merely change those settings instead of using tissue harmonic imaging. Of course, that is not the reality of clinical practice.

Tissue harmonic imaging reduces the level of clutter in the chamber of the left-ventricle relative to the level of tissue, thereby allowing one viewing the image to more easily differentiate the edges of the heart tissue shown in white (myocardium or septum) from the chamber of the ventricle shown in black.<sup>9</sup> Changing system or video monitor settings would affect both tissue signals and clutter equally and would not provide the improved contrast resolution seen in the Acuson Images. Additionally, while using a higher frequency and higher gain and power settings may be able to provide improved detail resolution and penetration depth, such settings would not also provide improved contrast resolution. Accordingly, the presence of improved contrast resolution along with improved detail resolution conclusively establishes that these improvements are the result of tissue harmonic imaging.

## **2. The Improvement in Contrast Resolution Is Not Contrast Agent**

Applicant also argues that the improved contrast resolution shown in the Acuson Images is the result of the leading tail of contrast agent entering the heart chamber. This

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<sup>9</sup> Contrary to Applicant's argument, improved clarity along the tissue edge *is* a characteristic of tissue harmonic imaging. Tissue harmonic imaging is used in cardiology to improve definition of tissue edges to differentiate between the inner lining of the myocardium and the ventricles. Dep. of Gregory L. Holley, Petitioner Page 118, line 18 - Petitioner Page 119, line 1.

argument is contrary to basic anatomy. As discussed in Petitioner's brief, the curved white area is near the *top* of the image, while the leading tail of contrast agent arrives in the heart chamber from the valve shown at the *bottom* of the image.<sup>10</sup> Contrast agent couldn't get to the top of the heart image without coming from the bottom—and it would be shown in the image. If the curved white area at the top of the image were really the leading tail of contrast agent, a concentration of contrast agent would be seen in the image between the curved white area and the valve shown at the bottom of the image. However, no such contrast agent concentration is seen in the Acuson Images.

The curved white area is exactly what Mr. Holley and Ms. Main testified it to be — the edge of the right-hand lateral portion of the left-ventricle wall (the septum) and the apex of the heart. Tissue harmonic imaging reduced the level of clutter in the chamber of the left-ventricle relative to the level of tissue, allowing these edges to be clearly defined in the Acuson Images.<sup>11</sup> Thus, the Acuson Images are Tissue Harmonic Images.

### **3. The Whole Tissue Mass Is Imaged in the Acuson Images**

Applicant argues that the Acuson Images are not Tissue Harmonic Images because the entire tissue mass is not imaged. Applicant's only proffered support for this argument is that the overall appearance of the Acuson Images and the images currently displayed on Acuson's web page look different. Despite this difference in appearance, the entire tissue mass *is* imaged in the Acuson Images. Mr. Holley identified several

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<sup>10</sup> Dep. of Gregory L. Holley, Petitioner Page 71, lines 16-25; Petitioner Page 84, lines 17-22; and Petitioner Page 106, lines 9-25.

<sup>11</sup> Dep. of Gregory L. Holley, Petitioner Page 86, line 23 - Petitioner Page 87, line 11; Petitioner Page 118, lines 18-22; and Petitioner Page 127, line 21 - Petitioner Page 128, line 1.

tissue components located *throughout the entire image frame*, which proves that the entire tissue mass is imaged.<sup>12</sup>

Q. Mr. Holley, in paragraph 5, you indicate that the Acuson tape around frame D includes a component that is visually perceptible with the unaided eye and that was formed from the second harmonic response of biological tissue as a result of finite amplitude distortion. Can you point to that visually perceptible component?

A. Yes, I can. In Exhibit 8, in the right-hand side . . . [y]ou can see the heart, you can see the septum of the heart, you can see the apex, you can see the left ventricle, you can see some valves.

Because the whole tissue mass is imaged, the question regarding the differences between the Acuson Image and the images on Acuson's web page is merely one of quality — not content. As explained in Petitioner's brief, one would expect the quality of the images on Acuson's web page to be better than the Acuson Images because the web page images were produced several years after the Acuson Images were acquired. The improvements in imaging technology over those years can account for the improved image quality shown in the images on Acuson's web page. Although less photogenic than the web page images, the Acuson Images are, nonetheless, Tissue Harmonic Images.

**4. The Acuson Images Are Not Merely Harmonic Images of Tissue**

Applicant also argues that the Acuson Images are harmonic images of tissue but not Tissue Harmonic Images. The primary basis for this argument is a quote from Dr. Chandler that the input transmit pulse had a high contribution of frequencies in the five megahertz region. However, Applicant failed to reveal that Dr. Chandler later clarified this statement by testifying that the energy in this region did not dominate the tissue

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<sup>12</sup> Dep. of Gregory L. Holley, Petitioner Page 71, lines 7-24.



harmonic response.<sup>13</sup> Further, Applicant did not mention that Dr. Chandler explicitly testified that the Acuson Images were generated from the tissue harmonic response.<sup>14</sup>

Additionally, Applicant's need to mischaracterize Mr. Holley's testimony underscores the weakness of its argument. Applicant weakly argues that it is significant that Mr. Holley did not use the term "Tissue Harmonic Image" in one excerpt comprising 16 lines of his 123-page deposition transcript.<sup>15</sup> But in this portion of his deposition, Mr. Holley is explaining the improved detail resolution he described in one of his earlier declarations. Applicant failed to mention that Mr. Holley's earlier declaration explicitly stated that the improved detail resolution Mr. Holley was referring to at his deposition is a characteristic feature of a Tissue Harmonic Image.<sup>16</sup>

### **III. THE PUBLICLY USED TISSUE HARMONIC IMAGES RENDER APPLICANT'S METHOD AND SYSTEM CLAIMS UNPATENTABLE**

In its brief, Applicant argues that evidence of publicly used Tissue Harmonic Images is insufficient to render unpatentable claims that are directed to a method and system used to produce a Tissue Harmonic Image. Applicant's argument is contrary to the Examiner's prior findings and to the law of public use.

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<sup>13</sup> Dep. of Paul E. Chandler, Petitioner Page 303, line 20 - Petitioner Page 304, line 3 and Petitioner Page 316, lines 14-22.

<sup>14</sup> Dep. of Paul E. Chandler, Petitioner Page 311, lines 12-17 ("the harmonic images on the tape . . . were generated, at least in part, by finite amplitude distortion as the term was used in the Ted Christopher publication. The Ted Christopher publication is talking about tissue harmonics").

<sup>15</sup> Dep. of Gregory L. Holley, Petitioner Page 86, line 23 to Petitioner Page 87, line 13.

<sup>16</sup> Sec. Evid. Dec. of Gregory L. Holley ¶ 6, Petitioner Page 11 ("The improved detail resolution . . . [is] characteristic of a Tissue Harmonic Image.).

**A. The Examiner Already Determined That Publicly Used Images Are Sufficient to Render Applicant's Method and System Claims Unpatentable**

In its petition to institute this public use proceeding, Petitioner asserted that Tissue Harmonic Images were in public use.<sup>17</sup> In order to institute this proceeding, the Examiner determined that a *prima facie* case of public use of the pending *system and method claims* was established based on the asserted public use of *images*. Accordingly, the Examiner has already determined that the public use of images is sufficient to render Applicant's method and system claims unpatentable. Because the evidence has conclusively established that Tissue Harmonic Images were in public use, the pending method and system claims must now be rejected.

**B. The Tissue Harmonic Images Are a Public Use of the Method and System Used to Produce Those Images**

The publicly used Tissue Harmonic Images can be considered the "product" of Applicant's claimed method and system of imaging. The relevant law makes clear that Applicant's method and system claims should be rejected in view of the publicly used Tissue Harmonic Images. As discussed in MPEP 2133.03(a)(C):

[E]ven a "secret" use by another inventor of a machine or process to make a product is "public" if the details of the machine or process are ascertainable by inspection or analysis of the product that is sold or publicly displayed.

A number of method and system elements are readily ascertainable from the publicly used Tissue Harmonic Images. Petitioner does not have access to the pending claims of the Christopher application and, accordingly, is not in a position to discuss why

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<sup>17</sup> Petition under 37 C.F.R. § 1.292 for the Institution of a Public Use Proceeding, Page 3, March 20, 1998 ("As pointed out briefly in the preceding paragraphs, the enclosed declarations are evidence that ultrasound images of heart tissue . . . were in public use . . .").

each of the elements recited in Applicant's method and system claims is ascertainable from the publicly used Tissue Harmonic Images. However, the following are examples of some of the many elements that the public could have ascertained from the publicly used images. Any method or system claim reciting these elements is unpatentable under 35 U.S.C. § 102(b). Additional elements may also be ascertainable from or obvious in view of the publicly used images.

**1. Generating an Input Ultrasonic Signal**

The publicly used images teach a method and system for imaging that include the element of generating an input ultrasonic signal at a fundamental frequency. With respect to the Acuson Images, Mr. Holley and Ms. Main testified that the legends "Backscatter from tissue occurs at the transmitted frequency" and "2.5 MHz" around the image shown at time code 3:36:22 of Petitioner Exhibit No. 11 teach that an ultrasound system was used to generate the Acuson Images by transmitting ultrasound energy at a fundamental center frequency of 2.5 MHz.<sup>18</sup> Additionally, Mr. Holley testified that the label SEC HARM 5.0 MHz shown on the Mayo Clinic Images teaches that the ultrasound system was operating in second harmonic mode to transmit at a fundamental center frequency of 2.5 MHz.<sup>19</sup> The public also would have known that the generated input ultrasonic signal had negligible energy in the second harmonic bandwidth of the fundamental frequency to avoid interfering with the second harmonic response of contrast agent that arrived in the animal subject later in the study. As Dr. Chandler

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<sup>18</sup> Third Evid. Dec. of Gregory L. Holley ¶ 5, Petitioner Page 26; Sec. Evid. Dec. of Joan C. Main ¶ 17, Petitioner Page 19.

<sup>19</sup> Dep. of Gregory L. Holley, Petitioner Page 144, line 25 - Petitioner Page 145, line 21 and Petitioner Page 149, line 16 - Petitioner Page 150, line 8.

testified, the energy in the second harmonic bandwidth of the fundamental frequency was negligible in that it did not dominate the tissue harmonic response.<sup>20</sup>

**2. Directing the Input Ultrasonic Signal along  
a Propagation Path in a Sample while Maintaining  
the Sample Substantially Free of Contrast Agent**

Because an ultrasound image was shown, the public would have known that the input ultrasonic signal was directed into and along a propagation path in the sample and was focused on a specific area of the sample. The lack of contrast agent visible in the Acuson and Mayo Clinic Images makes clear that the sample was maintained substantially free of any contrast agent while directing the input ultrasonic signal into and along the propagation path in the sample.<sup>21</sup> As the input ultrasonic signal propagated along the propagation path in the sample, the sample inherently caused finite, non-linear amplitude distortion of the input ultrasonic signal and produced a distorted ultrasonic signal having a second harmonic component.

**3. Receiving and Forming an Image  
Principally from the Second Harmonic  
Component Reflected by the Sample**

The Acuson and Mayo Clinic Images teach that an ultrasound system was used to receive and form an ultrasound image principally from the second harmonic component reflected by the sample. With respect to the Acuson Images, Mr. Holley and Ms. Main testified that the legends “Backscatter from bubbles can occur at multiples of the transmitted frequency” and “5.0 MHz” at time code 3:49:20 of Petitioner Exhibit No. 11

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<sup>20</sup> Dep. of Paul E. Chandler, Petitioner Page 303, line 20 - Petitioner Page 304, line 3 and Petitioner Page 316, lines 14-22.

<sup>21</sup> Third Evid. Dec. of Gregory L. Holley ¶ 10, Petitioner Page 28; Sec. Evid. Dec. of Joan C. Main ¶ 20, Petitioner Page 20.


and the legend "The second multiple is commonly referred to as the second harmonic" at time code 4:04:14 of Petitioner Exhibit No. 11 teach that the ultrasound system was receiving ultrasound echoes at a second harmonic center frequency of 5.0 MHz.<sup>22</sup> With respect to the Mayo Clinic Images, the label SEC HARM 5.0 MHz teaches that the ultrasound system was receiving at the harmonic center frequency of 5.0 MHz.<sup>23</sup>

#### **IV. CONCLUSION**

The only question before the Examiner is whether the publicly used Acuson Images or Mayo Clinic Images are Tissue Harmonic Images. The evidence has conclusively established that they are, and this evidence has not been rebutted by Applicant. The pending method and system claims should now be rejected under 35 U.S.C. § 102(b) alone or in combination with 35 U.S.C. § 103.

Dated: July 10, 2001

Respectfully submitted,



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<sup>22</sup> Third Evid. Dec. of Gregory L. Holley ¶ 6, Petitioner Pages 26-27; Sec. Evid. Dec. of Joan C. Main ¶ 18, Petitioner Page 19.

<sup>23</sup> Dep. of Gregory L. Holley, Petitioner Page 144, line 25 - Petitioner Page 145, line 21 and Petitioner Page 149, line 16 - Petitioner Page 150, line 8.


**PROOF OF SERVICE**

In accordance with 37 C.F.R. § 1.248, Petitioner hereby certifies that a duplicate copy of this paper has been served on Applicant's attorney on July 10, 2001 via first class mail at the following address:

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Dated: July 10, 2001

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